Remarks

Claims 1-15 are pending in the subject application. By this Amendment, Applicant has canceled claims 10-15 and amended claim 1. Support for the amendment to claim 1 can be found throughout the subject specification. Applicant has also amended the title of the subject application and amended the text in the specification to correct inadvertent typographical errors and reference to "BALB/c" mice as requested by the Examiner. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-9 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, the Examiner has indicated that the subject application is not in compliance with the requirements set for in 37 CFR 1.821-1.825 regarding applications containing sequence disclosures. Applicant respectfully asserts that an appropriate sequence identifier (SEQ ID NO:) has been designated for each sequence disclosed in the subject specification by way of a Preliminary Amendment filed in the subject application on January 3, 2003. Applicant respectfully requests that the Preliminary Amendment submitted on January 3, 2003 be considered and made of record in the subject application.

Claims 1-9 are rejected under 35 USC §102(e) as anticipated by Hoo (Patent No. 6,482,407). The examiner asserts that the Hoo patent teaches modified tumor cells as tumor vaccines which comprise CD40 and GM-CSF and IL-12. The Hoo patent is also cited as teaching inactivating the tumor cells. Applicant respectfully traverses this ground of rejection.

Applicant respectfully asserts that the Hoo patent does not teach or suggest Applicant's claimed invention. Claim 1 of the subject application specifies that the cells of the method are engineered to express soluble CD40. The Hoo patent does not teach or suggest anything regarding the use of a soluble CD40. Reference to CD40 in the Hoo patent pertains to use of the membrane attachment domain of CD40 (see columns 7 and 8 and Table 2 of the Hoo patent). The membrane attachment domain of CD40 is not soluble CD40. In soluble forms of CD40, the membrane attachment domain is absent or nonfunctional. Moreover, the Hoo patent contemplates that the membrane attachment domain is fused to a heterologous immunomodulatory molecule to provide a membrane-bound fusion protein (See Hoo patent Abstract). Thus, the Hoo patent contemplates the use of a membrane-bound (i.e., not souble) fusion protein in the vaccine composition. The only other reference to CD40 in the Hoo patent is

found at column 19, line 7, and does <u>not</u> mention the use of a <u>soluble</u> form of CD40. Thus, the Hoo patent does not teach or suggest the soluble CD40 element of Applicant's claimed invention. As the Examiner is aware, in order to anticipate under 35 U.S.C. §102, a <u>single</u> reference must disclose within the four corners of the document <u>each and every</u> element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(e) is respectfully requested.

It should be understood that the amendments presented herein have been made <u>solely</u> to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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